REMARKS

Claims 1-5, 9-14 and 18 are pending in the application. No claims have been amended. Applicants respectfully request reconsideration of this application in view of the following remarks.

Claim Rejection Under 35 U.S.C. § 112, ¶1

The Examiner rejected claimed 1-5, 9-14 and 18 under 35 U.S.C. § 112, ¶1, as failing to comply with the written description requirement. Specifically, the Examiner stated:

> "In the present case Applicant has no possession of the subject matter of claim 1 and its dependent claims including the for method of treatment of oncoses, uncontrolled proliferation, sarcoma, acute lymphatic leukemia (ALL) acute promyleotic leukemia (APL) Hodgkin's disease, lung carcinoma and many more by disorazole compounds of formula I as in claim 1. The specification provides test data for proliferation of three disorazole compounds A1, D1 and E1, the claims are too broad and disclosure does not provide guidance or direction for the treatment of all the diseases as claimed."

See the Office Action, page 5, ll. 4-10. It seems that the Examiner rejected claims based on lack of written description "for the treatment of all of the diseases as claimed."

However, not all of the pending claims are directed to methods of treatment. Specifically, claims 1-2 are directed to disorazole compounds, claims 3 and 14 are directed to a pharmaceutical composition containing disorazole compounds, claim 4 is directed to a method of treating oncoses, claim 5 is directed to a method of inhibiting mitosis, claims 9-13 are directed to a method of treating benign and oncoses, and claim 18 is directed to a method of treating tumor diseases. Applicants respectfully traverse the grounds of the Examiner's rejection as follows.

Claims 1-3 and 14

As set forth above, claims 1-3 and 14 are directed to disorazole compounds and their pharmaceutical compositions.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *See, e.g., Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991). According to Manual of Patent Examining Procedure ("MPEP"), § 2163.II, "[p]ossession may be shown by describing an actual reduction to practice of the claimed invention. Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention."

Here, Applicants not only describe an actual reduction to practice of making and using the claimed disorazole compounds, but also provide a clear depiction of the claimed compounds in structural chemical formulae. *See, e.g., Regents of University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997) ("In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus."). Accordingly, one skilled in the art would clearly recognize that Applicants had possession of the claimed disorazole compounds and their pharmaceutical compositions.

Claim 5

Claim 5 is directed to a method of inhibiting mitosis in rapidly and uncontrolledly proliferating endogenous cells by administering a disorazole compound.

Here again, Applicants' possession of claim 5 is shown by describing an actual reduction to practice of using disorazole compounds to inhibit proliferative cells and inhibit the cell cycles. *See* Examples 7-10.

However, it is the Examiner's position that "the specification provides test data for proliferation of three disorazole compounds A1, D1 and E1, the claims are too broad and disclosure does not provide guidance or direction for the treatment of all the diseases as claimed." The Office Action, page 5, ll. 8-10. Applicants disagree. As MPEP § 2163.II points out, "the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice ... A 'representative number of species' means that the species which are adequately described are representative of the entire genus." Although the specification only provides testing data for anti-proliferation of three disorazole compounds, these tested compounds share a general core structure of disorazoles, and therefore, are representative of the entire genus. Accordingly, one skilled in the art would recognize that Applicants had possession of the claimed method of inhibition with disorazole compounds.

Claims 4, 9-13 and 18

(A)

As set forth above, claims 4, 9-13 and 18 are directed methods of treating oncoses, benign or tumor diseases.

As discussed above, Applicants' possession of claims 4, 9-13 and 18 is shown by describing an actual reduction to practice of using disorazole compounds, *in vitro* and *in vivo*, to inhibit proliferation, to inhibit the polymerization of tublin, to inhibit cell cycles, and to reduce the tumor growth in mice. *See* Examples 7-11.

As the tested compounds are representative of the entire genus, one skilled in the art would recognize that Applicants had possession of the claimed method of treatment with disorazole compounds.[1]

(B)

With respect to the method of treatment claims, the Examiner also stated that "the disclosure provides no indication of whether the compounds treat all cancers. To make clearer **the lack of enablement** for treatment of all cancer, extrinsic evidence is supplied by Draetta ... the data as presented are not sufficient to **enable** such claims" (emphases added). The Office Action, page 5, l. 18 to pate 6, l. 8. Further, the Examiner alleged that "in the art of clinical oncology, no compound has yet shown clinical efficacy against every type of cancer ... one skilled in the art would not be able to make and use the invention." The Office Action, page 6, l. 9 to pate 7, l. 4. Clearly, although the Examiner rejected all pending claims under the written description provision of the first paragraph of 35 U.S.C. 112, the Examiner raised questions with respect to the enablement provision. The written description requirement is separate and distinct from the enablement requirement. *See, e.g., Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1562.

However, as discussed below, Applicants submit all pending claims are enabled.

Applicants would like to point out that as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of Section 112 is satisfied. *In re Fisher*, 427 F.2d 833, 839 (CCPA 1970). Here, Applicants not only provide general guidance on the use of the compounds of the invention for the treatment of oncoses, benign or tumor diseases

[1] The Examiner also states that "there is no example to use the compound with another 'antitumor agent' or signal transduction inhibitors." The Office Action, page 5, ll. 16-17. The use of the recited another antitumor

(*see* paragraphs [0038]-[0048]), but also present specific examples for *in vitro* testing the compounds of the invention for inhibition of the proliferation of various tumor cell lines (*see* Examples 7-8), for *in vitro* testing the compounds of the invention for inhibition of the polymerization of tubulin (*see* Example 9), for *in vitro* testing the compounds of the invention for inhibition of cell cycles (*see* Example 10), and for *in vivo* testing the compounds of the invention for inducing tumor growth in mice (*see* Example 11). "An *in vitro* or *in vivo* animal model example in the specification, in effect, constitutes a 'working example' if that example 'correlates' with a disclosed or claimed method invention." *See* MPEP §2164.02. Thus, one person skilled in the art, provided with the general guidance and specific examples in the specification directed against a variety of tumors, would have a reasonable expectation that a pharmaceutical composition containing the compounds of the invention would have efficacy in oncoses, benign or tumor diseases. Moreover, when the artisan is fully able to utilize claimed subject matter as described in the specification, clinical testing should not be made a prerequisite to patentability. *See In re Hartop*, 311 F.2d 249 (CCPA 1962) and *Ex parte Rubin*, 5 USPQ 2d 1461 (BPAI 1987).[2,3]

For at least the foregoing reasons, Applicants submit all pending claims are enabled.

---

agent and signal transduction inhibitors is described in the specification, para. [0008]. Thus, there is literal support for the recitation.

[2] The Examiner also stated that "there is no example to use the compound with another 'antitumor agent' or signal transduction inhibitors." The Office Action, page 5, ll. 16-17. However, "the absence of working examples will not by itself render the invention non-enabled." *See* MPEP §2164.02. The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908 (CCPA 1970). Here, it is well known to one skilled in the art that it would be useful to combine an antitumor drug with another antitumor agent or signal transduction inhibitor, then the specification need not contain an example.

[3] The Examiner further stated that "the disclosure provides no indication of whether the compounds treat all cancers" (emphasis added). The Office Action, page 5, ll. 18-19. However, Applicants do not claim the treatment of all cancers, but have specified oncoses in claim 4, benign or malignant oncoses in claim 9, and

CONCLUSION

In light of the foregoing, Applicants respectfully submit that all pending claims are now in condition for allowance.

Applicants submit herewith authorization to charge fees associated with the accompanying the Petition for Extension of Time. It is believed that no other fees are necessitated by the present Reply. However, in the event that any additional fees are due, the Commissioner is hereby authorized to charge any such fees to Deposit Account No. 06-0923.

If the Examiner believes that a telephone conversation with Applicants' attorney would expedite allowance of this application, the Examiner is cordially invited to telephone the undersigned attorney at the number provided below.

Respectfully submitted,

Date: February 4, 2008

Q. Hong Xu (Reg. No. 52,378)
Goodwin Procter LLP
599 Lexington Avenue
New York, New York 10022
Tel. No.: (212) 813-8839
Fax No.: (212) 355-3333

tumor diseases in claim 18. In any event, "[t]he presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled." *See* MPEP §2164.08.